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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/324,343	06/02/1999	JOHAN H. GEERKE	ALZA-0022 ARC-2865-R3	1409
23377	7590	07/14/2004	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/324,343

Applicant(s)

GEERKE ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Amendment filed on April 19, 2004 has been entered. Applicant had elected with traverse Group III, claims 18-31 in Paper No. 5 filed on April 24, 2000. The restriction requirement was made pursuant to reasoning on the Paper No. 4 filed on February 12, 2000. Claims 1-17 stand withdrawn from further consideration because they are directed to a non-elected invention.

Applicant's arguments were found persuasive. Accordingly, the rejection of record has been withdrawn in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al US Patent 5,248,310 ("Barclay") in view of Wong et al US Patent 5,785,994 ("Wong").

The instant claims are directed to three-layer tablets comprising a first and second layer that contains a drug and at least one colorant, and a third layer containing a second and different colorant. The dependent claim further adds a coating layer to said tablets.

Barclay teaches osmotic tablets comprising separate drug polymer and polymer layers wherein each layer is distinguishable from each other by a different color. (see abstract, col 20, lines 26-60). In col 17, lines 20-55, Barclay describes an osmotic tablet comprising a white color drug containing layer and a reddish brown hydrophilic polymer

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layer. Barclay describes the use of ferric oxide colorant as the colorant of choice.

Barclay further coats the tablet with a translucent coating and describes that the drug/beneficial agent layer is detectable through such translucent coating (col 5, lines 42-51). Since color difference is easily detectable by naked eye, Barclay's tablet inherently possess capability to be detected by an colorant detector. Barclay also teaches suitable size or shape for his tablets to allow comfortable oral delivery. (see col 6, lines 20-24, figures 1-3). Barclay does not teach a three layer osmotic tablet.

Wong teaches three-layered osmotic tablets containing a port (see abstract). At least one layer of Wong's tablets contains a dye such as ferric oxide. Wong discloses tablet dosage forms comprising three layers wherein first layer is drug free and is a push layer which contains a colorant such as ferric oxide (see col 17 line 23; col 20, lines 20-25) and the third layer comprise a colorant (see figure 3, col 16 lines 58-67, col 18 lines 1-42). The tablet of Wong comprises an exit port (see col 17 line 56) meeting the limitation of claims 25, 30 (see col 15 lines 15-18). Finally, Wong et al disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18).

Although, Therefore, it would have been obvious to one ordinary skilled in the art at the time of invention to employ Barclay's method of detecting different layers in the three layer osmotic dosage forms of Wong, by incorporating a coloring agent, as shown by Barclay, in any desired layer, because it is well described that different colorants facilitate ease of detection of each layer.

Claims 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay in view of Wong and further in view of Rork et al US patent 5,582,838 ("Rork") Misra et al US Patent 5,422,831 ("Misra").

The instant claims are directed to methods of making osmotic tablets comprising making a first and second layer containing a drug and a colorant and a third layer having a different colorant, and detecting the formulation orientation of the tablet with a color detector.

The teachings of Barclay and Wong are discussed previously. Their combined teachings does not specifically provide for methods of detecting the orientation of the tablet with a color detector.

Rork provides that colorants are conventionally employed in the art to detect orientation (faces) of osmotic tablets enabling a detector to identify the proper orientation (face) for drilling operation to make delivery apertures. (see col 10, lines 50-63).

Misra also teaches methods of employing color detectors for determining the quality of pharmaceutical products based on physical characteristics such as shape, hardness, color and surface (col 3 lines 29-40) using transducer signals. Misra teaches analysis of the color of the pills and detection of undesirable characteristics of a given dosage form (col 11 lines 5-50, col 13 lines 1-24).

Since methods of determining color characteristics of dosage forms by a detector, as taught by Rork and Misra, are conventional in the art; it would have been obvious to one of ordinary skill in the art at the time of invention to formulate a multi

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layer osmotic dosage forms having different color in each layer, as described by Barclay and Wong, and further study its orientation or other physical characteristics, as taught by Rork and Misra in order to optimize the aperture placement and drilling operation.

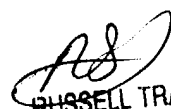
### ***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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